

REMARKS

Amendments to the Specification

1. The specification has been amended on page 10 to correct the misspelling of the word "views".

2. The use of the trademarks Lycra, Expancel and Vaseline is believed to be appropriate in that each word begins with a capital letter indicating recognition of its trademark status. The generic terminology for "LYCRA" is unknown, but it is known to be a fiber (not a fabric) made by DuPont. The generic descriptors for EXPANCEL and VASELINE have been introduced or already were included in the specification.

Amendment to the Abstract

The Abstract has been corrected.

Claim Rejections - 35 U.S.C. § 112

1. Claim 13 has been corrected.
2. Claim 17 has been canceled, thereby rendering moot the rejection of this claim under 35 U.S.C. § 112.
3. Claims 24-23 have been amended to provide a generic descriptor for the VASELINE brand of petroleum jelly.
4. Claims 29 and 30 have been canceled, and the rejection of these claims under 35 U.S.C. § 112 is now moot.

Claim Rejections - 35 U.S.C. § 102-103

1. The rejection of claims 31-33 is now moot in view of the cancellation of these claims. Applicant does not agree with basis for the rejection and reserves its options with respect to presenting these claims in another application for further consideration.

Claim Rejection - 35 U.S.C. § 103

1. Reconsideration of the rejection of claims 1-5 and 7 under 35 U.S.C. § 103(a) in view of Klasson '474 considered with Stockwell '735 and Evans et al. '118 is requested. The Examiner's detailed consideration of the patentability of claims 1-5 and 7 is noted with appreciation. The fact remains that the cited prior art considered individually or in any reasonably combination fails to teach, disclose or even remotely suggest the combination of:

- at least one cured silicone elastomer layer,
- containing silicone oil,
- and hollow microspheres dispersed throughout the elastomer layer.

The Examiner herself concedes that Klasson '474 fails to provide such a disclosure. Indeed, the Examiner acknowledges that Klasson fails to disclose numerous elements of claims 1-5 and 7.

Klasson particularly fails to teach the above-recited combination of claim 1 in combination with an elasticized fabric layer immediately bonded to one side of the silicone elastomer layer, as recited in claim 2.

Klasson '474 likewise fails to teach a configuration of the composite elastic material of claim 1 in the form of a tubular sleeve but with the silicone elastomer layer covering the inside wall of the sleeve and the elasticized fabric covering the exterior of the sleeve as required by claim 4.

Klasson '474, likewise fails to teach a reinforcement matrix for controlling distension of the composite elastic material imbedded in the silicone elastomer layer, as required by claim 5.

Klasson '474 also fails to teach the application of a prosthetic connector element imbedded in a cured silicone elastomer distal end cap adhered to the distal end of the suction liner as required by claim 7.

The Examiner furthermore acknowledges that Klasson '474 in view of Stockwell '735 fails to disclose the addition of the silicone oil to the silicone elastomer layer combined with hollow microspheres as recited in claim 1. The Examiner relies on

Evans as a broad teaching of an "oil extended silicone elastomer". The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a silicone oil as an extending material as suggested by Evans in the surface coating of Stockwell "in order to improve the processability and to optimize the properties of cured reinforced silicone elastomers."

The Examiner further contends that "it would have been obvious...to use the surface coating with hollow microspheres of Stockwell in the sleeve-shaped article of Klasson to provide thermal insulation while being flexible and light in weight...motivated by the expectation of successfully implementing the invention of Klasson".

It is respectfully submitted that the Examiner's arguments are necessarily based upon speculation and conjecture, as even the basic teachings or disclosures attributed to the document by the Examiner are missing entirely.

Evans discloses and teaches that the addition of silicone oils to "amorphous, high molecular weight silicone elastomers reinforced with high surface area fillers, as process aids,...and to optimize properties of cured reinforced silicone elastomers has not been practiced because of the severe reduction in the level of physical properties of the cured silicone elastomer compositions caused by even small amounts of such extender oils (col. 1, lines 24-34).

Thus, Evans clearly discloses that the use of extender oils, including silicone oils, reduces the physical properties of the cured silicone elastomer compositions of the type disclosed in a patent. Evans '118 then proceeds to describe a specific composition involving the use of silicone oils in a very specific environment and with very specific compositions of silicone elastomers, fillers, etc.

The Examiner is reminded that the present invention is intended to provide a novel, light-weight, soft elastomer material suitable for prosthetic applications, in particular prosthetic suspension or suction liners. Such liners, as clearly described in the specification, are located between a residual limb of an amputee and a hard outer socket intended to provide a rigid connection to a prosthetic appliance, such as a lower leg and a foot, for below-the-knee amputees. (An artificial knee may be provided in

combination with the hard socket for above-the-knee amputees).

For such applications, a degree of low strength in the elastomer is an accepted and desirable characteristic or attribute because it is advantageous to seal the limb against entry of air between the limb and the elastomer, and also to provide a very soft gentle cushion between the skin of the amputee and the hard outer socket.

Of paramount concern is the reduction of the weight of the prosthetic suction liner, which can be significant when relatively thick silicone elastomer layers are utilized to produce the suction liner. The novelty of the present invention lies in the discovery that hollow microspheres dispersed throughout the silicone elastomer layer containing silicone oil provides a very light weight yet effective elastomer composition for application in prosthetic devices such as suction liners or suction sleeves.

Accordingly, it is respectfully submitted that the disclosure of Evans '118 bears little or no relevance to the present invention.

Specifically, there would be no motivation whatsoever to a person of ordinary skill in the art to transfer, use or apply any teachings of the Evans '118 patent in combination with any of the teachings of Klasson in the '474 and Stockwell '735.

Contrary to the Examiner's supposition, it is clear on its face that the silicone oil disclosed in Evans '118 is intended for a very specific application involving various high molecular weight silicone elastomers reinforced with high surface area fillers. No such elastomers or fillers are described in Klasson or Stockwell and it is entirely unknown what effect the use of such silicone oils would have in the Klasson and Stockwell products, and in particular the Stockwell coatings. Stockwell fails to suggest the use of any kind of oil or extender in the patent.

It is respectfully submitted that the Examiner has failed to establish a *prima facie* case of obviousness based on regard to Klasson '474, Stockwell '735 and Evans '118.

For example, the Examiner suggests that the mythical person skilled in the art would be motivated to use the hollow microspheres of Stockwell in the sleeve-shaped article of Klasson "to provide thermal insulation while being flexible and light in weight." While the Examiner may be correct, thermal insulation properties have not been

discussed in connection with this invention and such properties are not even mentioned in the description. Clearly, the microspheres of Stockwell will result in a coating that is lighter than a similar coating without microspheres. However, Stockwell fails to appreciate that such composition, when combined with a silicone oil, can result in a composite elastic material useful for prosthetic applications, and specifically a tubular prosthetic suction liner or a tubular sleeve, wherein the silicone elastomer layer is expected to cover the inside area of the liner or sleeve.

With regard to claim 4, the Examiner reduces the combination of elements as if they were merely a reversal of working parts. With all due respect for the Examiner's stated opinion, the opinion entirely overlooks the properties of a cured silicone elastomer layer containing silicone oil and hollow microspheres when used as a prosthetic suction liner or a tubular sleeve. The silicone elastomer layer is very difficult to slide across bare skin because of its high friction or tacky properties. In many instances it must be rolled over the skin or residual limb and then adjusted in small increments to the extent that the silicone elastomer layer can be temporarily spaced away from the skin while being moved. Thus, claim 4 involves more than a simple reversal of essential working parts, because one skilled in the art would not appreciate that the Stockwell '735 fabric would function properly for its disclosed purposes if the silicone material was placed on the inside against the skin of a person. Indeed, one having experience with trying to draw a silicone elastomer material across the skin will readily presume that this is highly undesirable, particularly with regard to articles of clothing.

With regard to claim 5, it is to be noted that this claim recites a directional distention controlling reinforcement matrix embedded in the silicone elastomer layer containing the silicone oil and hollow microspheres. Nothing in any of the prior art whatsoever shows, teaches or remotely discloses this combination of elements.

The Examiner attempts to equate the metal-coated fibers of Stockwell '735 with the recited reinforcement matrix. What the Examiner overlooks is the fact that the metal-coated fibers of Stockwell are obviously random oriented or at the very least

placed within the coating mixture without regard to any distension limitation effects. The Examiner herself acknowledges the fact that "Klasson and Stockwell in view of Evans does not explicitly teach the claimed stiffness against elongation...". The Examiner then contends that "it is reasonable to presume that the reinforcement matrix provides stiffness against elongation of the liner". The Examiner then attempts to shift the burden to the applicant to prove that the presumed stiffness against elongation properties will not inherently result from application of the teachings of Stockwell.

It is respectfully submitted that the Examiner cannot shift the burden to applicant "to prove otherwise" until the Examiner has at least established a *prima facie* case of inherency or common sense result. Until there is some teaching somewhere in the Stockwell patent or generally in the prior art that at least suggests to the person skilled in the art that the metal-coated fibers could have sufficient length and orientation to provide some type of predetermined distension resisting property along some direction, no *prima facie* case can be established and no case of inherency can be established as well. It is patently unfair to attempt to shift a burden to applicant to prove that the metal-coated fibers of Stockwell could not have any such properties when there is absolutely no teaching or suggestion whatsoever that such properties could ever exist within the four corners of the Stockwell patent.

It seems that the Examiner supposes that somehow the metal-coated fibers of Stockwell possess some strength properties that inherently could have influence on the directional distension or directional strength properties of the disclosed composite elastomer material. A careful reading of the discussion of such metal-coated fibers in column 3, lines 31-41 on the other hand reveals that the metal-coated fibers are mentioned in the same context as "metal-coated platelets of glass or similar materials, metal shavings, or combinations thereof." Obviously, the metal-coated fibers are short reinforcing elements intended to be used as fillers having metallic properties other than directional elasticity limiting characteristics. Indeed, nowhere within Stockwell is there seen any teaching, suggestion or disclosure of limiting the directional distention properties of the coated compositions as a result of using a reinforcement matrix of the

kind recited in claim 5 of this application.

In view of the above comments, it is respectfully submitted that rejection of claims 1-5 and 7 in view of Klasson, Stockwell and Evans is inappropriate, unsupported by the cited prior art, and therefore legally insufficient. Withdrawal of the rejection is appropriate and is requested.

2. The rejection of claims 8-11, 37, 38, 39 and 41 under 35 U.S.C. § 103 as unpatentable in view of Klasson, Stockwell and Evans is respectfully traversed. There is no support in the cited prior art for the shape and form of a suction liner as recited in these claims. This geometry for a composite material has been discovered as a result of intense engineering analysis and experience. The configuration of a composite elastic material as recited in these claims and as illustrated in Figs. 6-10 of this application finds no counterpart whatsoever in any prior art. This geometry is extremely complex and has been carefully described both in words and in graphical representations as presented on pages 11 and 12 of the specification. It is incumbent on the Examiner to at least demonstrate the relevancy of the cited prior art with regard to the specific claim elements in order to support this rejection. The broad statement by the Examiner that "Klasson discloses a suction liner tapered towards the distal end wherein the circular liner with the distinct radii of curvature in the longitudinal axis as shown in Fig. 1 [of the patent]" provides a teaching of obviousness is in itself obviously deficient. Such a broad unsupported statement will not and cannot support a rejection of claim 8 and the same statement can be made with regard to claims 10, 11, 37, 38, 39 and 41. For example, the Examiner entirely overlooks and ignores the location of the first, second and third longitudinal axes recited in claim 8. Thus, the prior art, whether considered individually or collectively, fails to show, teach or remotely suggest such first, second, and third longitudinal axis and their geometric relationship with respect to the suction liner configuration recited in claims 8-11, 37-39.

With regard to claim 41, the Examiner has failed to establish an appropriate grounds for rejecting this claim, which recites the combination of compositions recited

in claim 8 wherein the composite elastic material has specified minimum tensile strength and 100% modulus. This is a very low tensile strength and a low range of 100% modulus. A composite material having a form of a suction liner as recited in claim 8 with such recited tensile strengths and range of moduli is not suggested or remotely disclosed in any of the prior art.

Accordingly, it is respectfully submitted that withdrawal of the rejection of claims 8-11 and 37-39 and 41 is appropriate and the same is respectfully requested.

3. Claims 12 and 13 (except claim 12/6) stand rejected as unpatentable over Klasson, Stockwell and Evans under 35 U.S.C. § 103. It is respectfully submitted that these claims are fully patentable over the prior art for the reasons stated previously with regard to claims 1-5 and 7 and furthermore because the specific combination of the material recited in claims 2, 3, 4, 5 and 7 in combination with the second cured silicone elastomer layer is not suggested or disclosed or taught by the prior art.

It is respectfully submitted that the rejection of claims 12 and 13 should be withdrawn.

4. Claims 15, 16 and 18-28 recite various properties of the composite elastic material of claims 1-7. It is respectfully submitted that the combined teachings of Klasson, Stockwell and Evans fail to remotely approach the structural combination of elements and the compositions recited in these claims. It is to be noted that a tensile strength of one Pa is extremely low and is suitable for applications such as in a soft cushion or pad material. Likewise, a 100% modulus of 5 to 30 kPa is also suited for soft, very stretchy materials. It is totally implausible to assume that such properties of an elastomer material are "inherent to Stockwell in view of Klasson". There is nothing whatsoever available to the reader of the Stockwell and the Klasson patents that would suggest an elastomer material having the properties recited in claims 15, 16, 18-28. The Examiner attempts to find support for the inherency argument by stating that "the use of like materials...would result in the claimed property." The Examiner entirely

overlooks the fact that the composite materials of Stockwell and Klasson are not the same composite elastic material as recited in the claims. Nothing in Stockwell or Klasson suggest that the elastomer of Stockwell and Klasson could include silicone oil and have a very low tensile strength and 100% modulus, as well as all of the other properties recited in claims 15, 16, 18-28. The argument of inherency must be supported by some observable inherent property of the Stockwell material that can be plausibly equated with the properties recited in the claims.

With regard to claim 15, there is nothing in Stockwell that would suggest to a person skilled in the art that the elastomer could have a minimum tensile strength of 1Pa and a 100% modulus of 5-30 kPa. Indeed, it would be entirely implausible to assume that such a low strength would be desirable in the Stockwell material based on the disclosure contained in the patent, which focuses on waterproofing and thermal insulation for garments.

With regard to claim 16, there is nothing contained in the prior art teaching the use of a nylon jersey knit having 28 needles per 2.5 cm, comprising 87% nylon, 13% Spandex, with said fabric substantially stretchable beyond its relaxed dimensions both lengthwise and widthwise.

With regard to claims 19 and 20, the prior art fails to disclose or suggest the combination of the composite elastic material recited in claims 1-7 wherein the microspheres have the density of $.005\text{g/cm}^3$ to 1.25g/cm^3 and specifically $.05\text{g/cm}^3$.

With regard claims 21 and 22, the prior art fails to show, teach or suggest composite elastic material as recited in claims 1-7 wherein the silicone elastomer layer comprises by weight:

- 50-99.4% silicone elastomer
- .5-45% silicone oil
- .1-5% microspheres.

With regard to claims 23-26, none of the prior art discloses or suggests the composition of claims 1-7 in combination with the skin treatment agents recited in claims 23-26.

With regard to claims 27 and 28, none of the prior art discloses or teaches the elastic material of claims 1-7 wherein the silicone elastomer layer has the properties recited in these claims. Specifically, the tensile strength of .1Pa minimum, a durometer of 13-62 and a 100% modulus of 5kPa to 250 kPa finds no counterpart whatsoever in the cited prior art, and is not indicated as being inherent in any of the prior art.

For the foregoing reasons, it is respectfully submitted that the rejection of claims 15, 16 and 18-28 is inappropriate and withdrawal of the rejection is respectfully solicited.

The Examiner has expressed the view that most if not all of the properties and characteristics of the elastic material recited in claims 15, 16 and 18-28 are simply "result effective variables". While such variables obviously will affect the properties of the composition, the selection of specific properties or values of such variables does not necessarily amount to an obvious expedient. The prior art does not teach such "obvious expedients" and the Examiner assumes that such expedients would be readily apparent and obvious to a person skilled in the art. It is respectfully submitted that the properties, materials, and compositions recited in claims 15, 16 and 18-28 represent specific discoveries and selections that would not be apparent to a person skilled in the art, particularly with regard to materials having prosthetic applications. The Examiner has failed to provide any connection whatsoever between the materials described in Stockwell '735 and the properties of these materials with a composite elastic material useful for prosthetic applications and shaped and formed in accordance with claims 1-7. Claims 15, 16 and 18-28 recite inventive features underlying a novel composite elastic material useful for forming prosthetic devices that is patentably distinctive over the combined teachings of Stockwell and Klasson.

With regard to the Examiner's reliance on Ogawa '578, with regard to claims 23, 24, 25, and 26 it is respectfully submitted that cosmetic compositions described as suitable for external applications directly on skin do not support a rejection of a claim for a composite elastic material wherein the silicone elastomer layer containing silicone oil and microspheres also contains a skin treating agent blended into the composition.

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At a minimum, it is incumbent upon the Examiner to establish a *prima facie* case of obviousness with respect to the teachings of Ogawa '578 and it is applicant's position that the Examiner has failed to establish a minimum case of obviousness based on the cited prior art. Withdrawal of the rejection of claims 15, 16, 18-28 is clearly warranted and the same is requested.

It is noted that the Examiner has allowed claim 6 and it is also presumed that claim 12/6 also has been determined by the Examiner to be allowable, provided that the claims are rewritten in appropriate independent form. Presentation of claims 6 and 12/6 in independent form is withheld pending a final determination with regard to the patentability of the remaining outstanding claims in the application.

Claims 33-35 have been withdrawn from consideration and certain claims have been canceled by this amendment to reduce the issues under consideration. Cancellation of the claims is not to be interpreted as a concession to the Examiner's grounds for rejection and applicant reserves all rights to pursue the subject matter of the canceled claims in continuing applications.

If any issues remain that can be readily resolved by a telephone conference with applicants' attorney, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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